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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,046	08/08/2001	Syed Hossainy	ACS 54307 (22561)	2624

7590 08/04/2003

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EXAMINER	
PANTUCK, BRADFORD C	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,046	HOSSAINY ET AL.	
	Examiner	Art Unit	
	Bradford C Pantuck	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 57-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14, 57-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2 & 3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

Applicant's election without traverse of Claims 1-14 and 57-64 in Paper No. 5 is acknowledged.

Specification

1. The disclosure is objected to because of the following informalities:

A Brief Description of the Several Views of the Drawing(s) is required: See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

Specifically, the Applicant has not made reference to Figures 6C-6E. Also, the Applicant has made reference to Figure 7F, which does not exist [see page 6]. Appropriate correction is required.

2. The disclosure is also objected to because component 312 of the invention is referred to as "inner surfaces" [page 11, line 4]. Throughout the application and claims, the Applicant recites a roughened area on the *inner surface* of the stent. In the Figures 6A-6E, however, the roughened areas appear to be on the *outer surfaces*. In fact, in the next sentence, the Applicant refers to the asperities on the opposite side from the said "inner surface 312" as "inner surface asperities 314". Two surfaces on opposite sides of an object cannot both be the inner surface. The Applicant's terminology is contradictory, and is, seemingly, a typographical error.

Appropriate correction is required.

3. The disclosure is also objected to because of the typographical error on page 10, line 11: "fort he three-dimension".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 3 recites the limitation "the lens" in line 2. There is insufficient antecedent basis for this limitation in the claim. Additionally, it is not understood what is meant by the term "lens."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,938,766 to Jarvik. Jarvik discloses an implantable vascular prosthesis (1b) with

a body portion and a roughened area formed on its inner surface [Column 12, lines 41-43; see Fig. 4].

6. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,883,618 to Barrows. Regarding Claim 1, Barrows discloses an implantable medical device. It was implanted in rats and is used to repair nerves [Column 3, lines 15-20; Column 18, lines 55-60]. Barrows' device has a body portion and a roughened inner portion [Column 4, lines 34-40].

7. Regarding Claim 3, Barrows discloses depositing material on the inner surface of the implantable medical device. Specifically, he discloses applying material in "particulate form." The material causes the inner surface to be roughened. Barrows discloses using a mixture of different polymers. The tube may be made of woven or unwoven material [Column 8, lines 3-20].

8. Claims 1, 2, 4-7, 9-14, and 57-64 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,190,404 to Palmaz et al. Regarding Claims 1 and 11, Palmaz discloses an implantable medical device having a body portion and a roughened area on the inner surface of its body portion [see Fig. 8; Column 5, lines 1-8]. The plurality of grooves formed in the inner surface, as shown in Figures 9-15, cause the inner surface to be rough. That is, if one rubbed one's finger over the surface of the inside surface (301) of the stent, it would feel rough—i.e. *course* and not *smooth*.

9. Regarding Claim 2, the word *asperity* is defined as "roughness or harshness, as of a surface." Thus, the inner surface of Palmaz's device has asperities—rough portions—due to the crevices in its surface, as described above.

10. Regarding Claim 4, the inner surface of Palmaz's device is rough because material has been selectively etched from the body portion [Column 5, lines 9-17].

11. Regarding Claims 5 and 12, the roughened area of the inner surface (301) of Palmaz's stent (300) includes substantially the entire inner surface of the body portion. As shown in Figure 8, and explained in Column 5, lines 19-52, the grooves (400, 400', 400", 400"') of Palmaz's stent can cover as much of the interior surface of the stent as is desired. In addition to the grooves, the rectangularly shaped holes *interspersed throughout the body* of the stent will also contribute to the rough feel of the stent [see Fig. 8].

12. Regarding Claims 6 and 13, the stent of Palmaz has a middle portion of its inner surface that is smooth [see Attachment #1]. Note that the *exemplary* middle section is chosen to illustrate that there is a middle portion that is smooth in the inner surface Palmaz's device. There are other smooth portions in the middle of the inner surface Palmaz's stent, as well. Specifically regarding Claim 13, the first and second ends of Palmaz's stent have *selected roughened regions* on the interior surface. Palmaz discloses that the designer of the stent may choose, *i.e. select*, how many/which kind of grooves to put on the interior surface of the stent [Column 6, lines 45-51].

13. Regarding Claims 7, 59, 60, 62, and 63 the roughened portion Palmaz's tubular stent has a "roughness factor" greater than 40 nm. The Applicant, in the Specification

discloses that 40 nm is the "upper limit of roughness factors typical of *polished stent surfaces*" [page 9, lines 28-29]. In other words, correctly polished stents for medical uses will have roughness factors less than 40 nm. Therefore, a stent with an *unpolished surface* or, *even more so*, a surface having *grooves* in it, must have a roughness factor, as defined by the Applicant [Equation 1, page 10], of greater than 40 nm. Palmaz's stent has an inner surface with asperities, as discussed above, and will have a roughness factor of much greater than 40 nm.

14. Regarding Claims 9, 14, 57, 58, and 61 Palmaz discloses coating the inner surface of his stent with a non-thrombogenic material. His coating is a *layer* (218) of endothelial cells, which covers the inner surface of the stent [Fig. 7; Column 5, lines 56-62], separating the asperities on the inner surface of the stent from the flowing blood. Palmaz explains that he is intending to form a *layer of cells*, not just a few scattered cells coating the interior of the stent [Column 1, lines 54-58; Column 4, lines 32-36]. Endothelial cells are the cells that coat the inner surfaces of natural blood vessels and the heart. When these cells are removed, platelets form. Platelets are the kind of cells that are *thrombogenic*, i.e. cause clotting. Endothelial cells *prevent thrombosis,* i.e. non-thrombogenic, and allow the interior of the stent to remain open [Column 1, lines 35-65].

15. Regarding Claim 10, Palmaz's stent has a body portion (300). The roughened portion of the stent (300) includes the flat inner surface (301) of the stent with the intervening grooves (400). The depth of each groove is .5-10 microns, which is a depth less than the thickness of the body portion (300), as shown in cross-sectional

Figures 9-25. For example, Figure 10 shows very clearly that the depth of the groove (400) is less than the thickness of the wall between the inner and outer surface. Therefore, the roughened portion includes a region (i.e. at each groove) where the wall is thinner than the selected thickness.

16. Regarding Claim 64, the inner surface of Palmaz's device is rougher than the outer surface, because the inner surface has many grooves, whereas the outer surface has none. Although the rectangularly shaped holes interspersed throughout the body of the stent will increase the roughness of the outer surface, they will equally increase the roughness of the inner surface. The *inner surface has grooves in addition to the holes*, and will consequently be rougher.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,190,404 to Palmaz et al. Palmaz does not specifically disclose the roughness factor of the inside surface of his stent being above 100 nm, but it can be inferred that his roughness factor [as defined by the Applicant] is greater than 100 nm, as explained below. As previously explained, the Applicant, in the Specification

discloses that 40 nm is the "upper limit of roughness factors typical of *polished stent surfaces*" [page 9, lines 28-29]. In other words, correctly polished stents for medical uses will have roughness factors less than 40 nm. Therefore, a stent with an *unpolished surface* or, *even more so*, a surface having *grooves* in it, must have a roughness factor, as defined by the Applicant [Equation 1, page 10], of greater than 40 nm. Palmaz's stent has an inner surface with asperities, as discussed above, and will have a roughness factor of much greater than 40 nm. The grooves in Palmaz's stent .5-10X10(-6) meters deep and 2-40X10(-6) meters wide. Therefore, Palmaz's stent has significant grooves and because the difference between 40 nm and 100 nm is so minute, it is clear that the interior of Palmaz's stent will be *significantly* rougher than a polished metal surface with a roughness of 40 nm.

Further, Palmaz's grooves have substantially the same shape as the Applicant's grooves. For example Palmaz's Figure 12 is very similar to the Applicant's rendering of the shape of his grooves in Figure 6E. Palmaz *discloses the same grooves as the Applicant*, and discloses arranging the grooves in as great a frequency as is desired [Column 5, lines 36-43]. Although it is unclear what dimensions the grooves of the Applicant's inner surface have, Palmaz discloses having the same grooves on the interior of his stent as the Applicant, so consequently his roughness factor must be assumed to be the same as the Applicant's: over 100 nm.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 4,632,396 to Taylor

U.S. Patent No. 4,869,714 to Deininger et al.

U.S. Patent No. 6,209,915 B1 to Fagan et al.

U.S. Patent No. 6,290,720 B1 to Khosravi et al.

U.S. Patent No. 6,254,632 to Wu et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

BCP
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July 25, 2003

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